K092079

Attachment B
Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92(c)

AUG 0 6 2009

GE Healthcare

General Electric Company
3000 N. Grandview Blvd., Waukesha, WI 53188

Section a):

1. Submitter: GE Healthcare
3000 N. Grandview Blvd., W450
Waukesha, WI 53188
USA

Contact Person: James T. Turner, MS, RAC
USA Premarket RA Leader
Telephone: 262-544-3359; Fax: 414-908-9225

Date Prepared: June, XX 2009

2. Device Name: GE Vivid S5 and Vivid S6 Diagnostic Ultrasound System
Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN
Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO
Diagnostic Ultrasonic Transducer, 21 CFR 892.1570, 90-ITX

3. Marketed Device: GE Vivid S5 and Vivid S6 Diagnostic Ultrasound System, K071985 currently in commercial distribution.

4. Device Description: The GE Vivid S5 and Vivid S6 are mobile ultrasound consoles having a wide assortment of electronic array transducers intended primarily for echocardiography with additional capability in vascular and general ultrasound imaging. Its intuitive user interface, high level of auto-optimization along with significantly reduced size and weight make it readily maneuverable, efficient and easy to use.

5. Indications for Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal/Obstetrics; Abdominal/GYN; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transesophageal; Transrectal; Transvaginal; and Intraoperative (abdominal, thoracic, and vascular).

6. Comparison with Predicate Device: The modified GE Vivid S5/S6 is of a comparable type and substantially equivalent to the current GE Vivid S5/S6. It has the same overall characteristics, key safety and effectiveness features, physical design, construction, and materials, and has the same intended uses and operating modes as the predicate device and additional software features that are similar to other cleared GE Ultrasound systems.

7. **Section b):**

1. Non-clinical Tests: The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.

2. Clinical Tests: None required.

3. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820, and ISO13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Healthcare that the GE Vivid S5/S6 Diagnostic Ultrasound is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

GE Medical Systems Israel, Ultrasound, Ltd.
% Mr. James T. Turner
USA Premarket RA Leader
GE Healthcare, QARA Regions - Americas
3000 N. Grandview Blvd., W450
WAUKESHA WI 53188

AUG 0 6 2009

Re: K092079
Trade/Device Name: GE Vivid S5 and Vivid S6 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: July 7, 2009
Received: July 9, 2009

Dear Mr. Turner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE Vivid S5/S6 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

4C-RS	10S-RS
8C-RS	M4S-RS
E8C-RS	6Tc-RS
8L-RS	i12L-RS
12L-RS	6S-RS
7S-RS	9L-RS

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Robert Ochs at (301) 796-6661.

Sincerely yours,

for

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	P	
Abdominal [1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ (specify)[2]	P	P	P		P	P	P	P	P	P	
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	
Other[4]	P	P	P	P	P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P	P	
Transrectal	P	P	P		P		P	P	P	P	
Transvaginal	P	P	P		P	P	P	P	P	P	
Transurethral											
Intraoperative (specify)[5]	P	P	P		P	P	P	P	P	P	
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA on Vivid S5/S6 (K071985); E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic and Renal.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[5] Intraoperative includes abdominal, thoracic, and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD, B/Color M.
[♦] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K092079

Diagnostic Ultrasound Indications for Use Form
GE Vivid S5/S6 with 4C-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P		P	N	P	P	P	P	
Abdominal[1]	P	P	P		P	N	P	P	P	P	
Pediatric	P	P	P		P	N	P	P	P	P	
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	N	N	N		N	N	N	N	N	N	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	P	P	P		P	N	P	P	P	P	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication – Peripheral Vascular application previously cleared on Vivid 7 BT05 (K051449);
P = previously cleared by FDA on Vivid S5/S6 (K071985); E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic and Renal.
[4] Other use includes Urology.
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD, B/Color M.
[♦] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K092079

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 8C-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	P	P	P		P	N	P	P	P	P	
Pediatric	P	P	P		P	N	P	P	P	P	
Small Organ (specify)[2]	P	P	P		P	N	P	P	P	P	
Neonatal Cephalic	P	P	P		P	N	P	P	P	P	
Adult Cephalic											
Cardiac[3]	N	N	N		N	N	N	N	N	N	
Peripheral Vascular	P	P	P		P	N	P	P	P	P	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication – cardiac indication previously cleared on GE LOGIQ Book Ultrasound (K032477);
P = previously cleared by FDA on Vivid S5/S6 (K071985); E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic and Renal.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD, B/Color M.
[♦] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K092079

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with E8C-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P		P	N	P	P	P	P	
Abdominal[1]	P	P	P		P	N	P	P	P	P	
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	P	P	P		P	N	P	P	P	P	
Exam Type, Means of Access											
Transesophageal											
Transrectal	P	P	P		P		P	P	P	P	
Transvaginal	P	P	P		P	N	P	P	P	P	
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA on Vivid S5/S6 (K071985); E = added under Appendix E

Notes: [1] Abdominal Includes GYN/Pelvic and Renal.
[4] Other use includes Urology.
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD, B/Color M.
[♦] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K092079

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 8L-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	P	P	P		P	N	P	P	P	P	
Pediatric	P	P	P		P	N	P	P	P	P	
Small Organ (specify)[2]	P	P	P		P	N	P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	N	P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P	N	P	P	P	P	
Musculo-skeletal Superficial	P	P	P		P	N	P	P	P	P	
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA on Vivid S5/S6 (K071985); E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic and Renal.
[2] Small organ includes breast, testes, thyroid.
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD, B/Color M.
[♦] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K092079

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/6 with 12L-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric	P	P	P		P	N	P	P	P	P	
Small Organ[2]	P	P	P		P	N	P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P	N	P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P	N	P	P	P	P	
Musculo-skeletal Superficial	P	P	P		P	N	P	P	P	P	
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative [5] (specify)	P	P	P		P	N	P	P	P	P	
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA on Vivid S5/S6 (K071985); E = added under Appendix E

Notes:

[2] Small organ includes breast, testes, thyroid.
[5] Intraoperative includes abdominal, thoracic), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD, B/Color M.
[♦] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K092079

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 7S-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal [1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ (specify)											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	
Adult Cephalic											
Cardiac[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular	N	N	N	N	N	N	N	N	N	N	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	P	P	P	P	P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication - previously cleared by FDA on Vivid i/q (K082374);

P = previously cleared by FDA on Vivid S5/S6 (K071985); E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic and Renal.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD, B/Color M.
[♦] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K092079

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 10S-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ (specify)											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular	N	N	N	N	N	N	N	N	N	N	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication -previously cleared by FDA on Vivid I/q (K082374);

P = previously cleared by FDA on Vivid S5/S6 (K071985); E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic and Renal.
[3] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD, B/Color M.
[♦] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K092079

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with M4S-RS Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics	N	N	N	N	N	N	N	N	N	N	
Abdominal[1]	N	N	N	N	N	N	N	N	N	N	
Pediatric	N	N	N	N	N	N	N	N	N	N	
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic	N	N	N	N	N	N	N	N	N	N	
Cardiac[3]	N	N	N	N	N	N	N	N	N	N	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication, (Transducer previously cleared on Vivid 7 BT05 (K051449)); P = previously cleared by FDA;
E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic and Renal.
[3] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD, B/Color M.
[♦] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K092079

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 6Tc-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	N	N	N	N	N	N	N	N	N	N	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal	N	N	N	N	N	N	N	N	N	N	
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication (Transducer previously cleared on Vivid i/q K082374); P = previously cleared by FDA;
E = added under Appendix E

Notes:
[3] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD, B/Color M.
[♦] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092079

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with i12L-RS Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	N	N	N		N	N	N	N	N	N	
Pediatric	N	N	N		N	N	N	N	N	N	
Small Organ (specify)[2]	N	N	N		N	N	N	N	N	N	
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	N	N	N		N	N	N	N	N	N	
Peripheral Vascular	N	N	N		N	N	N	N	N	N	
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N	N	
Musculo-skeletal Superficial	N	N	N		N	N	N	N	N	N	
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]	N	N	N		N	N	N	N	N	N	
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication (Transducer previously cleared on LOGIQ 9 (K011188)); P = previously cleared by FDA;
E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic and Renal.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[5] Intraoperative includes abdominal, thoracic, and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD, B/Color M.
[♦] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K092079

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 6S-RS Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics	N	N	N	N	N	N	N	N	N	N	
Abdominal[1]	N	N	N	N	N	N	N	N	N	N	
Pediatric	N	N	N	N	N	N	N	N	N	N	
Small Organ (specify)											
Neonatal Cephalic	N	N	N	N	N	N	N	N	N	N	
Adult Cephalic											
Cardiac[3]	N	N	N	N	N	N	N	N	N	N	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication (Transducer previously cleared on Vivid E9 (K081921); P = previously cleared by FDA;
E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic and Renal.
[3] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD, B/Color M.
[♦] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092079

Diagnostic Ultrasound Indications for Use Form

GE Vivid S5/S6 with 9L-RS Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse♦	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	N	N	N		N	N	N	N	N	N	
Pediatric	N	N	N		N	N	N	N	N	N	
Small Organ[2]	N	N	N		N	N	N	N	N	N	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	N	N	N		N	N	N	N	N	N	
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N	N	
Musculo-skeletal Superficial	N	N	N		N	N	N	N	N	N	
Other (specify)											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication (Transducer previously cleared on LOGIQ P5 (K060993));

P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN/Pelvic and Renal.
[2] Small organ includes breast, testes, thyroid.
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD, B/Color M.
[♦] Coded Pulse is for digitally encoded harmonics.

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